

REMARKS

Election/Restriction

On page 2 of the Office Action the Examiner states, "As all the claims have been amended to recite methods of treating a skin microcirculatory disorder, the restriction requirement is withdrawn." However, the status of the claims lists claims 8 - 10, 15, 17 and 18 as withdrawn for not being drawn to the elected invention. Applicants respectfully request clarification.

Specification

The title has been amended to address the typographical error.

Claim Objections and Rejections under 35 USC §112

Claims 13, 14 and 19 have amended to address the Examiners objections. The structures of formulae (I), (II) and (III) have been replaced with clear figures.

Rejections under 35 USC §102

Claims 1, 7, 11, 14, 16 and 19 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Ghisalberti (WO 01/17497).

Ghisalberti (WO 01/17497) describes a cosmetic and/or dermatological composition and a method for the treatment and/or prevention of hyperpigmented skin. Ghisalberti's composition comprises 3-hydroxypyr(id)one derivatives.

On page 5 of the Office Action, the Examiner alleges that Schlerotherapy results in "red" pigmentary spots. This is not correct. In Example 2, Ghisalberti discloses the treatment of "post sclerotherapy spots" and not "red" pigmentary spots as alleged. On page 3, lines 7-45 Ghisalberti describes that one consequence of sclerotherapy is hyperpigmentation.

Ghisalberti only deals with the treatment of hyperpigmented skin which results from an excess of melanin and/or by hemosiderin deposits, thus making the skin turn to a

brown colour. Hyperpigmented skin is defined on page 5, lines 12-14 of Ghisalberti as skin impairments showing spots or areas of a dark colour, either due to an excess of melanin and/or to hemosiderin deposits. On page 1, Ghisalberti makes reference to dark spots which were previously treated with peroxides, melanin/tyrosinase synthesis inhibitors, hydroquinones and the like. Indeed, such products are effective in whitening/lightening hyperpigmented dark spots present on the skin. Hyperpigmented skin (i.e. dark, brown spots or marks on the skin) is associated with sclerotherapy. See for example the attached Ingenta abstract regarding post-sclerotherapy pigmentation, which states: "This pigmentation is brown and represents haemosiderin and sometimes melanin as well." Furthermore, spots that are hemosiderinic in nature do not arise from bleeding as alleged by the Examiner on page 5. Hemosiderin is defined as a dark yellow-brown pigment. See attached definitions from Mosbys Dental dictionary and Merriam-Webster dictionary.

As the Examiner notes on page 6 of the Office Action, "Ghisalberti does not disclose the use of these compounds for treating other skin conditions such as rosacea or purpura." Skin microcirculatory disorders are characterized by red spots and marks due to the perception of superficial blood flow and bleeding under the skin. Pathologies caused by skin microcirculatory disorders are not similar to the hyperpigmentation disorders disclosed in Ghisalberti. Ghisalberti is silent regarding the treatment of treating a skin microcirculatory disorders. Ghisalberti is particularly silent regarding treatment of purpura, rosacea capillaritis, rosacea, cutaneous vasculitis, itching purpura, purpura annularis telangiectodes, contact allergy skin capillaritis, traumatic skin hemorrhage or actinic purpura.

Rejections under 35 USC §103

Claims 1 - 7, 11-14, 16 and 19 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Ghisalberti ('497 above) in view of Murad (US Patent 6,630,163).

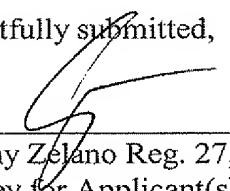
As noted above, Ghisalberti is silent regarding the treatment of treating skin microcirculatory disorders. Ghisalberti is particularly silent regarding treatment of purpura, rosacea capillaritis, rosacea, cutaneous vasculitis, itching purpura, purpura annularis

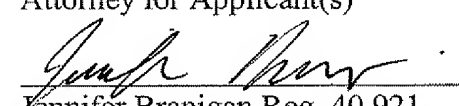
telangiectodes, contact allergy skin capillaritis, traumatic skin hemorrhage or actinic purpura.

Murad et al. (US 6,630,163) teaches the use of fruit extracts for neutralizing free radicals. The fruit extracts can be administered for the management of dermatological conditions such as senile purpura, rosacea and hyperpigmentation (see Col 7, line 45 - 49 and Col. 8 lines 5-9). Murad does not teach or suggest the compounds of the present invention. Murad et al adds nothing to the teachings of Ghisalberti and does not cure the deficiencies of the present invention.

Thus, in view of the above, it is respectfully requested that the rejections under 35 USC 102.103 be withdrawn.

Respectfully submitted,



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Persistent post-sclerotherapy pigmentation due to minocycline. Three cases and a review of post-sclerotherapy pigmentation



Author: Green D.

Source: Journal of Cosmetic Dermatology, Volume 1, Number 4, December 2002, pp. 173-182(10)

Publisher: Blackwell Publishing

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Abstract:

Summary Background

Post-sclerotherapy pigmentation, usually overlying the treated veins and independent of any drug ingestion, is common. This pigmentation is brown and represents haemosiderin and sometimes melanin as well. It usually slowly fades over a period of months, only uncommonly persisting for years.

Cutaneous pigmentation due to minocycline ingestion is a known but rare adverse effect. It usually appears as a round or irregular shaped patch that is dark blue to black, representing minocycline moieties and iron complexes. Its persistence for years is common.

Clinically and histopathologically, these two causes of pigmentation are quite distinct. In the absence of ulceration, minocycline pigmentation koebnerised by sclerotherapy has not previously been reported. Aims

To determine the nature of the pigmentation appearing in three patients who had been taking minocycline at the time, or shortly after, they had received sclerotherapy. Clinically, although this pigmentation had the usual distribution observed after sclerotherapy, it was persistent and appeared dark blue to black. Results

The persistent post-sclerotherapy linear pigmentation observed in all three patients had the characteristics of minocycline pigmentation. Conclusions

This is the first report of such minocycline-aggravated post-sclerotherapy pigmentation. Persistent post-sclerotherapy pigmentation caused by minocycline is a risk associated with ingestion of this drug. Patients need to be warned of this risk because, unlike post-sclerotherapy pigmentation that develops in the absence of drug ingestion, minocycline-aggravated post-sclerotherapy pigmentation may persist for years.

Keywords: haemosiderin; hyperpigmentation; minocycline; pigmentation; post-sclerotherapy; sclerotherapy



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hemosiderin /he-mo-sid-er-in/ (he7mo-sid'er-in) an insoluble form of tissue storage iron, visible microscopically both with and without the use of special stains.

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he-mo-sid-er-in (hē'mō-sīd'ēr-in)

n.

An insoluble protein that contains iron and that is produced by phagocytic digestion of hematin and found as granules in most tissues, especially in the liver.

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hemosiderin (hē'mōsid'ar-in),

n an intracellular storage form of iron; the granules consist of an ill-defined complex of ferric hydroxides, polysaccharides, and proteins having an iron content of approximately 33% by weight. It appears as a dark yellow-brown pigment.

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hemosiderin

an insoluble form of intracellular storage iron, visible microscopically both with and without the use of special stains.

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References in periodicals archive

Foam cells with vacuolated cytoplasm may be present, and they often have pigmented cytoplasmic granules containing hemosiderin.
Endolymphatic sac tumor, a report of 3 cases and discussion of ... by Maceri, Dennis / Ear Nose and Throat Journal

Dramatic decreases in bone marrow hemosiderin levels have been reported in some distance runners.
Gastrointestinal (GI) bleeding in endurance runners by Feller, Edward R. / AMAA Journal

These observations included the presence of pale, shiny, skin, thickened nails, little hair growth, cool skin temperature, weak or absent foot pulses, and the presence of varicosities or visual identification of skin stained with dark brown hemosiderin pigment, or bilateral limb swelling or lymphedema.
Effect of electrical stimulation on chronic leg ulcer size and ... by Harris, Kenneth A. / Physical Therapy



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Main Entry: **he-mo-sid-er-in**

Pronunciation: \hē-mō-'sī-də-rən\

Function: *noun*Etymology: International Scientific Vocabulary *hem-* + *sider-* + *-in*

Date: circa 1885

: a yellowish-brown granular intracellular pigment that is formed in some phagocytic cells (as macrophages) by the breakdown of hemoglobin and is probably essentially a denatured form of ferritin

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APA Style

hemosiderin. (2008). In Merriam-Webster Online Dictionary.

Retrieved May 27, 2008, from http://www.merriam-webster.com/dictionary/hemosiderin

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